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The purpose of this 4-year study is to determine the effects of the Comprehensive Coping Strategy Program (CCSP) on clinical outcomes and quality of life in breast cancer and their primary caregivers. Specifically, the purpose of this study was to compare descriptions of pain, psychological distress, fatigue, and perceived health status and burden of care in breast cancer patients who received autologous bone marrow transplant (ABMT) and their primary caregivers (PCGs) and participated in a CCSP and ABMT breast cancer patients and their PCGs who did not receive the CCSP. A randomized controlled clinical trial design was used. Thus far, 65 patients and 46 primary caregivers have entered the study. Forty three patients and their caregivers have been randomly assigned to the CCSP treatment group and 58 to the control group. Data were collected 35 days before (baseline), two days before the ABMT following administration of high dose chemotherapy and following ABMT at seven days and at 20 days or discharge. The CCSP intervention was given to the treatment group 14 days before the ABMT. The results showed trends that support the use of the CCSP in the reduction of pain and anxiety, depression and fatigue. The patients and their PCGs found the CCSP overwhelmingly helpful and used the CCSP in a variety of situations. The data appears to suggest that the CCSP maybe more effective when the patients symptoms are very intense (ABMT days -2 & +7).

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Fonnie Hunter Johnson
Principal Investigator's Signature

9/17/96
Date

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Introduction

Autologous bone marrow transplantation (ABMT) consists of the administration of high-dose chemotherapy and in some cases, total body radiation, followed by rescue with autologous, cryopreserved, bone marrow cells. This treatment regimen has become an established alternative treatment in a variety of malignant diseases including breast cancer[1]. While potentially life-saving, ABMT can be a traumatic procedure and can seriously impact the patient's quality of life (QOL). The often severe and unrelenting pain from the treatment regimen, medical procedures and persistent adverse physical side effects such as pain, fatigue and nausea and vomiting result in a critically ill and psychologically distressed patient. These symptoms in turn affect the patient's health status and QOL[2-3]. The patient's primary caregiver may also experience psychological distress, severe fatigue, increased burden of care, and a less than optimum QOL[4-9].

The overall purpose of this four year research project is to measure the effects of a comprehensive coping strategy program (CCSP) on pain, psychological distress, fatigue, perceived health status, burden of care, and QOL for breast cancer ABMT patients and their primary caregivers. The specific purpose of this paper is to present data from the first 20 months of study that describe pain, psychological distress, QOL, fatigue, perceived health status and coping in breast cancer patients who receive ABMT and burden of care, fatigue, psychological distress and QOL in primary care givers who participate in the CCSP and those who do not participate in the CCSP.

Literature Review

ABMT Patients

Pain associated with ABMT is well documented and is related to either the conditioning regimen and/or the ABMT procedure itself. Painful side effects of ABMT include the following: gastrointestinal complications- painful effects on the epithelial membranes of the oral cavity (stomatitis and ulcerations), gastritis, diarrhea and nausea and vomiting; genitourinary complications- painful effects on the mucosal epithelial membranes of the bladder wall (chemical cystitis), renal complications;; veno-occlusive disease; pancytopenia effects- infection, high fever, sepsis, hemorrhage; neurological complications; cardiac toxicities; alopecia with resultant effects on body image; and fatigue [2, 3, 10]. ABMT treatment causes pain through necessary invasive procedures such as bone marrow aspirations, spinal taps and Hickman Catheter placement. Rappaport[11] reported that anxiety and depression were the most common psychological reactions in patients post-ABMT. The subtle and overt interrelationships among the many potential physical and psychological symptoms related to ABMT make care of this population a very complex process.

As ABMT therapeutic advances for breast cancer have led to improvement in prognosis and overall survival, emphasis on the psychosocial well-being of the patient has become more important [12]. Anxiety regarding painful procedures, strict protective isolation, and depression were universal reactions during and for several months following ABMT[13]. Gaston-Johansson and associates[5] found that ABMT patients had moderate anxiety and depression during hospitalization and at discharge with anxiety and depression reaching peak intensity 5 days post ABMT. Jenkins and associates[14] found that 40% of ABMT patients, suffered from major depression at some stage during

the transplant procedure. Case studies and anecdotal description suggest that strict protective isolation, medical procedures, and pain are frequent contributors to anxiety and depression in ABMT patients, with pain described as the most frequent factor[14]. Research documenting a positive relationship of pain to anxiety and depression in cancer patients is extensive[15, 16].

About 33-76% of patients who undergo ABMT experience a high degree of fatigue[17]. Frequency and severity of pain, psychological distress and fatigue influences a patient's perceived health status, QOL and length of hospital stay[18]. Additional research targeting treatment-related fatigue and patient response to this symptom is needed [19].

Coping strategies of breast cancer patients have been recognized as a critical component of psychosocial well-being. Some of the psychological aspects of the BMT process are well-known: decreased contact with supportive persons because of protective isolation; anxiety related to the unpredictability of the progress through the BMT experience; and side effects[20]. Numerous factors affect psychosocial reactions to the BMT experience: age; social support; personality/intelligence; financial worries; religion; culture; and past experiences [21]. However, few longitudinal studies conducted over time to explore these factors have been completed[22]. Although few studies have been conducted to identify psychosocial aspects of the BMT experience from the patient's perspective, a hermeneutical inquiry was conducted which identified five major themes of coping patterns among BMT patients: physiological functioning; alertness; attitude; social relationships and; spirituality [20].

A patient's beliefs about his health status have been shown to be an important determinant of health outcomes[9]. The health status of ABMT patients vary. Some breast cancer ABMT patients leave the hospital within three weeks, while others stay 2-3 months. About 35% of patients utilize emergency room services and about 15-50% require one or more rehospitalizations[23].

Primary Caregiver (PCG)

It is well recognized that cancer impacts not only the patient, but also persons who comprise the patient's support system [24, 25, 26, 27, 28]. Northouse [28] presented summary empiric evidence from 19 studies that families may experience similar emotions as the breast cancer patient. The PCG is the person identified by the patient as the significant other. The PCG is usually the single greatest support person for the patient during the transplant process and at other difficult times[29]. Not only does the PCG devote energies to the patient during the pretransplant period and peritransplant period, but also because of the decreased length of stay for the ABMT patient additional responsibilities may be added: dispensing oral medications and administering intravenous fluids and medications via an infusion pump and; assessment of the patient in the home for sequelae of the ABMT process- fever, nausea and vomiting, diarrhea or other reportable side effects and symptomatology [30]. Few studies to date have documented the PCG's psychological distress or negative outcomes related to care of the breast cancer ABMT patient, or how they cope with problems related to caregiving burden. Pistrang and Barker [26] explored the role of the helping relationship with the partner related to women's psychological response to breast cancer. Their findings suggest that the partner plays a key role in breast cancer patients' adaptation and also that interventions focussing on couples may be effective in reducing psychological distress [26]. Burdens which can contribute to this distress include the patient's medical regimen, the constant/multiple patient demands prior to, during and

months/years after ABMT, possibly traveling long distances and displacement from home, friends and work, possibly living with a very ill person for a long time, and competing family/work responsibilities. There is some evidence that caregivers experience positive reactions [29]. However, most investigators suggest that caregivers responsibilities have negative effects on the caregivers' QOL[6]. Caregivers frequently demonstrate poor health and severe fatigue, in addition to frustration, anxiety and depression. Improving support within this close relationship may lessen PCG burden of care and allow for better adjustment to the cancer experience for both the patient and the PCG.

Comprehensive Coping Strategy Program (CCSP)

The Gate-Control Theory of pain by Melzack and Wall [15] and the Stress, Coping and Adaptation Paradigm by Lazarus[16] provide the theoretical framework for this study. Pain is defined as a multi-dimensional sensory and affective experience associated with discomfort[15]. Coping is defined as constantly changing cognitive and behavioral efforts used to manage specific external and /or internal demands that are appraised as taxing or exceeding the resources of a person[16]. Positive coping strategies refer to internal thoughts and behaviors people use to manage their pain, or their emotional reactions to the pain and to reduce emotional distress. Catastrophizing, a negative coping strategy, is defined as a method of cognitive coping characterized by negative self-statements and thoughts about the future[23,31]. Previous research studies have shown that pain and emotional distress can be reduced in pain patients by providing a comprehensive coping strategy program (CCSP) which includes: preparatory information to increase control[31]; b) cognitive restructuring which includes positive coping statements and avoidance of catastrophizing [31]; and c) relaxation with guided imagery. A combination of these three components has been found to be the best overall coping intervention to reduce pain and stress rather than using each component separately [31]. However, no prospective or retrospective study was found in the scientific literature which included these three components in a unified coping strategy program to reduce pain and emotional distress and fatigue in breast cancer ABMT patients.

The following questions were asked in this preliminary descriptive study:

1. How do breast cancer patients who receive ABMT and participate in a CCSP describe pain, psychological distress, fatigue, and perceived health status compared to breast cancer patients who receive ABMT but not the CCSP?

2. How do primary caregivers, of breast cancer patients who receive ABMT and participate in a CCSP, describe their burden of care, and psychological distress compared to primary caregivers of ABMT patients who do not receive the CCSP?

Methods and Instrumentation

Study Design

The study has a randomized controlled prospective clinical trial design with repeated treatment and measurements. Participants were randomized to one of two comparison groups for the purpose of measuring the effect of the proposed intervention, i.e. participation in the CCSP. Group I was composed of breast cancer patients and their PCGs who received the CCSP intervention. Group II included breast cancer patients and their PCGs who did not receive the CCSP. The initial preliminary effect of the CCSP was assessed by comparing differences in the means between the 2 groups in terms of the outcome measures. Eligibility criteria for participation in the project were as follows: 1) scheduled to receive ABMT for stage III or IV breast cancer; 2) able to speak and read English; 3) age $\geq$ 18; 4) able to identify a primary caregiver who is willing to participate in the study; and 5) able to give informed consent.

Patient Variables and Instruments

Socio-demographic and Background Variables

The information about demographic and background variables was collected on a standardized form and included the following information: age; gender; race/ethnicity; marital status; educational level; religion; household income; employment status; occupation; and whether the subjects lived alone or with another person.

Pain Intensity and Quality

The Pain-O-Meter® (POM) is a hard white plastic tool which measures 8 inches long, 2 inches wide and 1 inch thick. It is light weighted and can easily be held by the subject. A list of 15 sensory and 11 affective pain descriptors are located on the front side of the POM and a 100 mm visual analogue scale with a moveable marker is located on the back side of the POM (POM-VAS). An intensity value (from a low of one to a high of five) is pre-determined for each sensory and affective word located on front of the POM. A maximum score can be obtained for the sensory component of pain and for the affective component. A total score can be obtained by adding the sensory and affective scores. Test-retest reliability of the POM has been demonstrated as well as criterion related[34] and construct validity[32-36].

Psychological Distress

Anxiety and depression were assessed as measures of psychological distress. Anxiety was measured using the State-Trait Anxiety Inventory (STAI). The STAI consists of two separate self-report scales for measuring state and trait anxiety[37]. State anxiety is a transitory emotional response to a stressful situation. Trait anxiety reflects a stable predisposition to anxiety as determined by a personality pattern. Respondents rate themselves in relationship to the statement on a Likert scale

from 1 to 4. The total score is the sum of all 20 responses and ranges from a minimum score of 20-39 (low anxiety), 40-59 (moderate anxiety), to a maximum score of 60-80 (high anxiety). Test-retest reliability and validity have been demonstrated for the STAI[37]. Depression was measured using Beck's Depression Inventory (BDI). The BDI consists of 21 items that describe particular symptoms of depression [38]. Subjects respond to a Likert-type scale by rating each item 0 (no symptom) to 3 (severe or persistent presence of the symptom). Scores ranging from 0 to 9 are normal, 10 to 15 mild depression, 16 to 23 moderate depression, and 24 to 63 severe depression. The total score (range 0 to 63) is obtained by summing the 21 responses. Test-retest correlations of the BDI ranged from .60 to .90 in nonpsychiatric patients [38].

Fatigue

The Piper Fatigue Scale (PFS) was used to measure fatigue. This scale was designed to measure fatigue as a multidimensional phenomenon, defined as "a subjective feeling of tiredness, influenced by circadian rhythm, and other factors varying in duration, unpleasantness, and intensity" [39]. The scale consists of 41 horizontal 100 mm VAS items measuring four dimensions of subjective fatigue: 1) temporal dimension; 2) intensity/severity dimension; 3) affective dimension; and 4) sensory dimension. A total fatigue score is calculated by summing the four scores and dividing by four[39]. A 100 mm visual analogue scale was also used to measure overall fatigue.

Perceived Health Status

The Short-Form Health Survey (HS)[40] was used to measure perceived health status. The 20-item survey assesses physical functioning (6 items), role functioning (2 items), social functioning (1 item), mental health (5 items), health perception (5 items) and pain (1 item)[40]. Reliability[40] and construct validity has been demonstrated for the HS.

Coping Strategies

The Coping Strategy Questionnaire (CSQ), developed by Keefe[23], will be used to assess a person's use of pain coping strategies. The categories of coping strategies assessed by this measure include:1) diverting attention; 2) reinterpreting pain sensations; 3) ignoring pain sensations; 4) praying and hoping; 5) catastrophizing; and 6) increasing activity level. For each category of coping strategies there are 6 items on the CSQ with scores ranging from 0 to 36. Each item is rated on a 7 point scale to indicate how often that strategy is used to cope with pain (0 = never, 3 = sometimes, and 6 = always). The CSQ also includes 2 items which measure overall effectiveness of those strategies used by asking the subjects to rate on a 7-point scale (with scores ranging from 0 to 6) how much control they have over the pain, and how much they are able to decrease their pain[23]. Reliability and construct validity have been demonstrated for the CSQ[23].

Burden of Care

Burden of care (BOC) was assessed using the Measurement of Objective Burden (MOB) and the Measurement of Subjective Burden (MSB) scales developed by Montgomery, Gonyea and Hooyman[41]. The MOB is a 9-item, 5-point scale ranging from (1), " a lot more or better", to (5), "a lot less or worse", designed to assess the extent to which caregiving behaviors have changed the caregiver's lives in nine areas: time for oneself; privacy; money; personal freedom; energy; recreational/social activities; vocational activities; relationships with other family members; and health. The MSB is a 13-item, 5-point scale from (1) "rarely or never" to (5) "most of the time", designed to assess attitudes toward or emotional reactions to the caregiving experience. Items for the MSB were adapted from the 29-item inventory relating to attitudes and feelings about caregiving developed by Zarit and associates[42]. Reported alpha was .85 for the MOB scale and .86 for the MSB scale[41].

CCSP Intervention

Purposes

The three purposes of the CCSP are to: 1) teach the patient and PCG how to decrease and control pain and discomfort; 2) enhance the coping ability of the patient and PCG by teaching them to recognize distorted thinking, and how to use positive coping self-statements and; 3) teach the patient and PCG how to use relaxation with imagery. The goal of the CCSP is to reduce pain, psychological distress, and reduce fatigue that is known to be intensified by pain and psychological distress. A decrease in these symptoms is expected to positively influence the subjects perceived health status and QOL. A detailed description of the CCSP is presented in the Appendix A.

Data Collection Procedure and Administration of CCSP

This 4 year study has been in effect for 24 months and data have been collected over a period of 20 months. According to the study protocol, data are to be collected at 7 different time points at: a) baseline before the patient is hospitalized; b) 2 days before the ABMT; c) 7, and 20 days following the ABMT during hospitalization and; d) 3, 6 and 12 months following hospitalization. It takes about one year and 2 months for a complete set of data to be collected for each subject.

Baseline data were collected by the clinical nurse specialist -35 days of the ABMT. Two weeks prior to the ABMT (ABMT day -14), the CCSP intervention was taught to group I (treatment group) by a social worker experienced in teaching patients to use coping strategies and relaxation techniques. Group I (treatment group) patients and PCGs were instructed to practice the CCSP daily as well as before stressful situations. The treatment group was also instructed to record the following information in the Diary provided to each member of this group: a) Date/Time, situation, handout use, audiotape use and if these components of the CCSP were beneficial; b) Use of a VAS for the patient to rate pain and relaxation on BMT day -14, -2, +7, and +20 or discharge whichever occurs first; and c) use of a VAS for the PCG to rate relaxation on BMT day -14, -2, +7, and +20 or discharge whichever occurs first. The CCSP was reinforced in the patient's room by the research

nurse participating in the project on days -8 , -2 and +7 before the ABMT. Data were collected by a research assistant who administered the Pain-O-Meter® and standardized questionnaires to all subjects (patients and their PCG) in groups I (treatment) and II (control) during the patient's hospitalization. Data were collected on day -2 before the ABMT and at 7 and at 20 days or discharge following the ABMT in the patient's room.

A subset of data collected at baseline and two days prior to the ABMT was collected in this study.

Statistical Analysis

Descriptive statistics, correlational and chi square methodologies were used to analyze the data. Analysis of variance for (one way) has also used to compare group differences at baseline for demographic and psychological measures. The same procedure was also used to assess group differences between baseline and days -2 and +7 for longitudinal data comparison.

Results

In reporting the preliminary results from this study, consideration has been given to the fact that the results are influenced by a limited sample size. As can be seen in Table I, there were a total of 65 patients and 46 primary caregivers (PCG) participating in the study. Thirty one patients were randomized to the treatment group. Thirty four patients were randomized to the control group. Thus far, 65 patients and 46 primary caregivers have entered the study. Forty three patients and their caregivers have been randomly assigned to the CCSP treatment group and 58 to the control group.

[There were no significant differences between the groups for pain, psychosocial measurements at baseline table 2 column 1. There were no significant differences between the treatment and control group with regard to the major demographic variables]. The demographic characteristics of the sample are presented in Table l for the patients and their primary caregivers. The majority of the subjects were Caucasian with incomes of greater than $50,000. They were married, with a college degree or some college, living with their spouses, and actively employed. The mean age of the patients was 44, and 46 for the primary caregivers.

[Data collection was initiated in January of 1995. Our second year annual report represents 11/2 years of the data collection (January 1995 - July 1996). Technically we should have had 37 patients and 37 controls during this time period. This means that we should have had 74 patients and 74 PCGS. We have reported on an accrual of 65 patients and 46 PCG's. The reason for the discrepancy in the dyad for patients and PCG's is that 17 of the patients who were single or divorced, were initially able to identify a significant other who later on declined to participate in the study.] (See Table 1).

[Patient retention: when the project started, only one physician was responsible for recruitment of ABMT patients. Since September 1996 there are 3 physicians participating in ABMT program and recruiting subjects to the project. Johns Hopkins Hospital is presently increasing its capacity to increase the volume of ABMT patients through early discharge. Given the changes that have occurred since our 2 year report we anticipate to acquire the projected sample size by 1997. Retention in the study has posed some difficulties mainly due to death of the patient at different time points, the psychological and physical seriousness of the patients' condition, and lost-to-follow-up.

We are addressing the lost-to-follow-up problem by contacting the patients between 6 months to 2 years from baseline to collect data . This will give us a long term assessment of the CCSP intervention as well as improving sample retention.] At the time of our report there was not enough data in an adequately statistical manner the differences between the groups at one year.

EVALUATION OF THE CCSP INTERVENTION: CCSP PATIENTS & PCGs

PROCESS EVALUATION

Patients Usage of CCSP Audiotapes And Handouts

Very high percentages were reported by the patients regarding the usefulness of the CCSP audiotapes and the handouts. The audiotapes were used more frequently than the handouts. The patients recorded the use of the CCSP in the Diary during different times of day and in a variety of situations. The CCSP audiotape was mainly used in the evenings, just prior to bed time (N=33) and; in the hospital setting (N=100). The most frequent reasons that the patients gave for using the CCSP intervention were: for psychological stressful situations (N=54); to combat side effects of treatment and procedures (especially chemotherapy) (N=39) and; to induce sleep (N=23).

Pain Before and After The CCSP Intervention

The mean pain scores in the treatment group were lower after the CCSP intervention than before the intervention at all measurement points except for day +7 (Fig.1). As expected the pain gradually increased overtime and reached it's peak on day +7.

Relaxation Before and After the CCSP Intervention

The relaxation scores in both patients and PCGs in the treatment group were higher following the CCSP intervention than before the intervention at all measurement points (Figures 2 & 3). The level of relaxation was similar between the patients and the PCGs. Mean scores ranged from 6 to 7.54 before, and 7.38 to 9.27 after the CCSP intervention in patients. Mean scores in the PCGs ranged from 6.58 to 6.88 prior to the CCSP intervention, and 8.86 to 9.52 after the intervention. Prior to the CCSP intervention the patients reported their lowest scores for relaxation two days before the ABMT and 7 days following the ABMT.

PATIENTS IN TREATMENT AND CONTROL GROUPS

Correlations Among Symptoms At Baseline

There were significant correlations among the major variables of the study. Pain, anxiety, depression and fatigue were related to each other as was catastrophizing to each of these symptoms (Table IV). A decrease in quality of life was significantly related to an increase in anxiety and depression and; an decrease in the patient's ability to decrease pain (Table IV). Additionally, comparison between patients and controls in all symptoms revealed no significant differences at baseline.

Symptoms (pain, anxiety, depression and fatigue)

The means, standard deviations (SD) for pain, anxiety, depression, and fatigue are presented in Table II. In both the treatment and control groups, pain gradually decreased over time. Anxiety and depression were at their lowest levels on days -2 and +7 for the treatment group and at their highest levels on those days for the control group (Figs 4,5,6). [Anxiety was lower in the treatment group compared to the control group on day + 7 ($P<0.07$)].

Fatigue increased over time in the treatment group than in the control group on days -2 and +7 (Table II' Fig. 7).

[When the above measures were compared longitudinally (baseline vs days - 2 and +7) no significant differences were observed between the groups]. (Table V).

Health Status

The mean scores for the subcategories of health status followed the same pattern as anxiety, depression, and fatigue with scores somewhat more favorable on days -2 and +7, (Table II). The mean scores were similar in the treatment and control groups. The CCSP treated group reported slightly higher means for their health status on the sub-categories (social; and for health perception) for ABMT days -2 and +7 than the control group (Figs. 8-12). Health perception showed a greater difference between the means of the CCSP group and the control group with the CCSP group having higher means. There were significant improvements on the subscale social for health status for days - 2 ($P < .07$) and +7 ($P < .05$) for the treatment group compared to the control group]. (Table V).

Coping

Catastrophizing was at it's lowest level on day +7 in the treatment group. The control group had the lowest level of catastrophizing at discharge and it's highest level on day -2. Mean scores for catastrophizing were lower in the CCSP treated group than in the control group (Fig.13). Both the CCSP treated group and the control groups reported similar patterns for the coping skills with very little changes in mean scores over time (Table II). [The treatment group showed a marked difference on day +7 ($p<.09$) in catastrophizing compared to the control group]. (Table V). Noticeable differences in mean coping scores between the groups were seen for "reinterpreting pain" which was higher in the control group and "praying and hoping" which was higher in the CCSP treated group (Figs. 14 & 15).

PRIMARY CAREGIVERS

Primary caregivers in the CCSP treated group reported lower anxiety scores over time with the highest mean score at baseline and the lowest score at discharge. The PCGs in the control group reported a similar pattern of anxiety. The mean difference between the two groups was 12.13 at discharge with the PCGs in the control reporting a higher level of anxiety.

With regard to depression, the PCGs in both group reported stable scores for depression over time. However, the PCGs in the control group had lower scores than the CCSP treated group. The mean difference in the depression scores at discharge was 5.34 with the subjects in the control reporting lower scores (Table III). Fatigue scores were similar in both groups of PCGs except for at discharge where the CCSP treated group reported a higher mean score at discharge than at ABMT day +7.

The objective and subjective burden of care remained stable over time with similar scores at baseline and at discharge in both groups. Quality of life measures also remained stable over time in the sub-categories of Health, socioeconomic, and psychological/spiritual. The CCSP treated group reported a similar score for " family " quality of life at baseline and at discharge. The control group reported a somewhat lower "family" quality of life at discharged compared to baseline. The mean difference between the quality of life sub-category family scores for the CCSP treated group and the control group was 2.70 (Table III).

Discussion

Several cautions need to be kept in mind with the interpretation of these preliminary findings. Although the demographic characteristics of the sample appear to be comparable at this point in time, the limited sample size does not permit us to control for intervening factors such as severity of illness, trait anxiety, and health locus of control. Nor does the sample size permit us to make an appropriate statistical analysis of differences between the CCSP treated and the control groups. Consequently, the direct impact of CCSP over time cannot be evaluated at this time.

Thus far, however; most of the preliminary descriptive and correlational data seem to be promising and in line with expectations.

Usefulness of the CCSP

The patients and PCGs overwhelmingly reported that they found the CCSP intervention helpful. They used the CCSP intervention during critical points in their treatment and on days when they experienced most side effects from the ABMT. The subjects used the CCSP in situations that are supported theoretically in the scientific literature for use of behavioral treatment strategies such as to decrease their psychological distress, to decrease side effects of treatments and procedures, and to induce sleep. Although the CCSP was mainly used during the evenings, it was also used during the day.

The patients used the CCSP audio-tapes more frequently than the CCSP handouts. However they found the handouts to be equally as helpful as the audio-tapes. The increased use of the audio-tapes may be explained by the fact that it is a procedure that has to be followed whereas the handouts support cognitive restructuring. Hopefully, the information in the handouts gradually becomes an automatic part of the subjects' thinking processes and therefore do not need to be read so frequently. The audio-tapes make relaxation possible through the participation of subjects in a carefully outlined progressive relaxation procedure. The audio-tapes are also designed to help the subjects become relaxed more quickly as they become more comfortable with the information and instructions on the tape.

The patients in the CCSP group reported lower mean pain scores after the CCSP intervention at all time points except for day +7. As we know from other studies[5], pain reaches it's peak on about day +7 and that this is the worse day for the patient with regard to other symptoms. It is difficult to explain why the pain did not decrease on day +7 as it did on the other days after the CCSP intervention.

The preliminary results supported our expectations that the subjects using the CCSP would relax more after the use of the CCSP regardless of the circumstances or ABMT day. This was true for both patients and PCGs. We also expected that the patients and PCGs would find the CCSP useful. Although the patients received supervision to verify that they actually used the CCSP at certain points in time, the patients were very independent and used the CCSP intervention on their own and did not need to be supervised. The preliminary results from this part of the study offers some information that may be helpful in making the CCSP intervention more efficient. After an initial teaching of the CCSP intervention in a group of patients and PCGs, an audio-tape with all of the CCSP information, and training exercises could be given directly to the patients and PCGs. Other methods for disseminating this information, such as computer assisted learning, might also be considered if the final results of the study are in line with the preliminary findings.

Patients and PCGs in the CCSP Treatment and Control Groups

The symptoms associated with ABMT were more severe on ABMT days -2 and +7. These preliminary findings are supported by other studies[5]. Except for the pain scores, the mean scores for the other symptoms, psychological distress (anxiety and depression), and fatigue, are less intense at measurements -2, and +7 in the CCSP treated group. The control group follows a expected pattern of changes in symptom intensity over time. The most intense symptoms in the control group were on ABMT days -2 and +7 with a decrease in intensity at discharge.

The above findings may suggest that the CCSP is effective when the symptoms are more intense and provides some information towards answering the questions: "Under what condition is the CCSP most effective?"; " When should the CCSP intervention be used?" It could be that the CCSP intervention is effective when the symptoms are more severe (ABMT days -2, and +7), and the pattern of change that we are seeing in the symptoms are the effects of the CCSP intervention in the treatment group.

The pattern for the intensity of anxiety over time in both groups of PCGs was similar in that they became less anxious over time with the CCSP treated PCGs moving from moderate anxiety at baseline to mild anxiety. There was no change in the level of anxiety in the PCG control group. Both groups of PCGs experienced mild depression at each measurement point. The PCGs in both groups reported above average objective and subjective burden of care. Preliminary results suggest that fatigue is a common problem experienced by the PCG of a patient undergoing a bone marrow transplant.

The preliminary results suggest that the CCSP treated group was not using catastrophizing on ABMT days -2 and +7 as much as at other points in time when data were collected, or as much as the control group on the same ABMT days. This finding offers support that the patients are using the CCSP intervention on days -2 and +7 when they are sickest. The significant correlations reported between catastrophizing and pain, anxiety and depression, and fatigue support the theoretical bases for using the CCSP intervention. The avoidance of catastrophizing is a central theme of the CCSP intervention and is associated with decreased pain, anxiety, depression and fatigue.

The most notable difference between the CCSP and the control groups was related to health perception. The CCSP group perceived their health as being slightly better on ABMT days -2 and +7 which is logical since they reported less symptoms on those days as well as less use of

catastrophizing. How one perceives one's own health status is extremely important with regard to well being and recovery. As was seen in the correlations presented, the patient's perceived health status was related to pain, anxiety, depression and fatigue. The preliminary findings are in line with the results of other studies.

Conclusions

Although the sample size is too small to reach statistical inference from the data with regard to differences in the CCSP treated group and the control group, some exciting preliminary data are surfacing. Thus far, the majority of the findings are in the expected direction, and in line with the findings from previous studies. New information may be produced by this study in that the data may identify when it is appropriate to use the CCSP. It appears that during ABMT days -2 and +7 when the patients are experiencing their most severe symptoms, the CCSP might be most effective. [Although statistical significance was not achieved for many outcomes, the results are encouraging. Large mean differences between groups indicate possibility of achieving significance in the difference between groups when adequate statistical power is obtained through the increase in sample size, adjustment for covariates and repeated measures analysis].

The patients and PCGs found the CCSP overwhelmingly helpful; used the intervention at different time points during the ABMT, and in different situations independent of project personnel or hospital staff and; selected appropriately situations to use the CCSP.

[The research team is in the process of writing three manuscripts to be submitted for publication. These manuscripts are based on baseline data].

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Table I: Baseline Socio-Demographic Characteristics of Patients and Primary Caregivers Receiving CCSP and Their Controls

	Patients		Primary Caregivers	
Variables	**Treatment**	**Control**	**Treatment**	**Control**
Age	44 6	44 7	44 7	47 11
Gender				
Female	31	34	2	9
Male			20	15
Race				
White	28	28	22	21
African-American	2	4		3
Hispanic		1		
Native American	1			
Asian		1		
Marital Status				
Married	27	21	21	20
Single	2	7	1	4
Divorced	2	6		
Education				
High School	5	8	3	6
Some College	7	11	4	5
College Graduate	12	9	11	8
Graduate Degree	7	6	4	5
Religion				
Catholic	7	8	5	7
Protestant	14	18	11	8
Jewish	4	1	3	
Other	4	5	1	6
None		2	1	3

Table I: **Baseline Socio-Demographic Characteristics of Patients and Primary Caregivers Receiving CCSP and Their Controls (*continued from first page*)**

	Patients		Primary Care Givers	
Variables	**Treatment**	**Control**	**Treatment**	**Control**
Lives with:				
Spouse	27	19	21	18
Significant Other		3		1
Child	1	3		
Self	2	9	1	4
Work				
Full-time	19	18	19	18
Part-time	5	4	1	1
Unemployed, resigned	4	2	1	1
Unemployed, disability	1	4	1	1
Unemployed, retired	2			
Other		6		3
Occupation				
Professional	17	18	17	10
Technical	2	4	1	5
Retired	1		1	3
Other	7	9	3	6
Income				
< $20,000	1	2		3
$20,000 - $29,999		4	2	2
$30,000 - $39,999	3	3		1
$40,000 - $49,999	3	3	3	4
> $50,000	21	20	17	14

Table II. Pain, Psychological Distress, Coping and Health Status Measures Among Patients Receiving CCSP (Tx) and Their Controls (C) at Baseline, 2 days before ABMT, and 7 days after ABMT

Measures	Grp	Baseline N	Baseline Mean	Baseline SD	Day -2 N	Day -2 Mean	Day -2 SD	Day +7 N	Day +7 Mean	Day +7 SD
A. Symptoms										
1. Pain	Tx	31	4.16	1.27	19	4.16	1.17	19	3.37	1.16
	C	34	4.09	1.33	25	3.80	1.41	27	3.44	0.97
2. Stait Anxiety	Tx	31	40.63	11.45	21	34.68	8.39	19	33.45	9.95
	C	34	39.62	11.99	25	41.23	11.40	27	39.53	11.68
3. Depression	Tx	34	10.72	6.18	21	10.37	6.10	20	9.43	5.75
	C	31	12.38	8.94	25	13.37	8.32	27	12.38	7.43
4. Vas-Fatigue	Tx	30	28.53	23.71	20	44.30	24.31	22	42.09	24.71
	C	34	33.94	26.03	26	48.92	28.04	27	46.04	25.96
B. Coping										
1. Coping Self Statements	Tx	31	22.26	5.59	20	18.10	6.02	20	16.85	6.34
	C	34	22.96	6.71	25	18.76	5.08	27	19.74	8.96
2. Catastrophising	Tx	31	5.74	5.91	21	7.86	12.17	20	4.10	5.22
	C	34	5.88	5.24	28	11.50	16.53	27	9.07	9.49
C. Health Status										
1. Social Functioning	Tx	31	4.55	1.61	19	4.84	1.26	19	4.26	1.94
	C	34	5.15	1.16	24	4.63	1.28	26	3.58	1.65
2. Health Perception	Tx	31	14.74	5.59	19	14.63	5.05	19	15.32	4.69
	C	34	14.09	3.94	25	13.28	4.10	27	13.59	4.63

Table III: PCGS Receiving CCSP Treatment (Tx) And Their Controls (C).

Variable		Baseline Mean	Baseline SD	Day - 2 Mean	Day - 2 SD	Day + 7 Mean	Day + 7 SD	Discharge Mean	Discharge SD
A. Symptoms									
1. State Anxiety	Tx	42.34	9.77	39.62	11.68	37.67	12.44	22.53	13.14
	C	38.67	10.59	37.72	8.73	34.10	10.29	34.66	11.51
2. Depression	Tx	8.82	6.95	9.40	5.68	8.00	5.06	9.37	7.07
	C	6.21	3.80	4.94	3.42	4.66	3.70	4.03	3.41
3. Fatigue	Tx	34.18	18.15	37.42	18.33	33.49	18.90	45.89	19.72
	C	25.49	15.39	30.16	16.49	28.09	14.01	26.28	16.71
B. Burden of Care									
1. Obj. BOC	Tx	34.00	3.56	33.60	3.53	33.91	3.94	34.78	5.56
	C	32.46	3.28	32.19	3.67	31.00	5.69	31.91	3.18
2. Subject BOC	Tx	38.90	9.12	36.51	3.07	36.93	2.93	36.83	4.47
	C	37.34	3.87	36.83	3.77	37.15	2.32	36.89	3.25
C. Quality of Life									
1. Health	Tx	14.05	0.95	____	____	____	____	14.38	1.39
	C	14.01	0.95	____	____	____	____	14.19	0.89
2. Socio-Economy	Tx	12.99	1.88	____	____	____	____	12.59	2.17
	C	12.82	1.73	____	____	____	____	12.51	0.99
3. Psychological/ Spinchial	Tx	15.68	1.04	____	____	____	____	15.65	1.34
	C	15.07	0.84	____	____	____	____	14.87	0.30
4. Family	Tx	20.63	2.48	____	____	____	____	19.50	2.87
	C	19.80	3.67	____	____	____	____	16.80	2.56

Tx= Treatment Group
C= Control Group

Table IV. Correlation Among Measures of Pain, Fatigue, Coping and Psychological Distress in Patients Receiving ABMT and their Controls at Baseline (N=65)

Measures	1	2	3	4	5	6	7	8	9
1. Anxiety	1.0								
2. Depression	0.58***	1.0							
3. Pain (Health Status)	-0.01	-0.35**	1.0						
4. VAS-Fatigue	0.20	0.31***	0.21	1.0					
5. Piper Fatigue	0.46***	0.51***	0.32**	0.45***	1.0				
6. Ability to Control Pain	-0.22	-0.18	0.01	-0.01	-0.06	1.0			
7. Ability to Decrease Pain	-0.14	-0.21	0.20	-0.03	-0.11	0.75***	1.0		
8. Catastrophising	0.30*	0.40**	0.36**	0.25*	0.19	-0.12	-0.20	1.0	
9. Family	0.25	0.32*	0.04	0.09	0.23	-0.27*	-0.24	-0.12	1.0

*** P<0.05 ** P<0.01 *** P<0.001**

Table V. Preliminary Assessment of CCSP and Patient Outcomes for Days -2 and +7

		Day -2 - Baseline			Day +7 - Baseline		
Measures	Grp	N	Mean	P	N	Mean	P
A. Symptoms							
1. Pain	Tx	19	-0.53	.63	19	-0.89	.69
	C	25	-0.28		27	-0.70	
2. Anxiety	Tx	21	-2.11	.14	19	-4.90	.07
	C	25	2.03		27	0.42	
3. Depression	Tx	21	0.72	.94	20	-0.38	.75
	C	25	0.58		27	0.23	
4. Fatigue	Tx	20	18.55	.54	21	16.05	.93
	C	26	17.08		27	16.70	
B. Coping							
1. Coping Self Statements	Tx	20	-4.20	.72	20	-5.80	.27
	C	25	-3.42		27	-2.61	
2. Catastrophizing	Tx	21	3.00	.58	20	-0.65	.09
	C	28	5.32		27	3.26	
C. Health Status							
1. Social Functioning	Tx	19	0.15	.07	19	-0.47	.05
	C	24	-0.62		26	-1.69	
2 Health Perception	Tx	19	-1.47	.51	19	-0.42	.94
	C	25	-0.60		27	-0.52	

Fig. 1

Pain Score Before & After Intervention

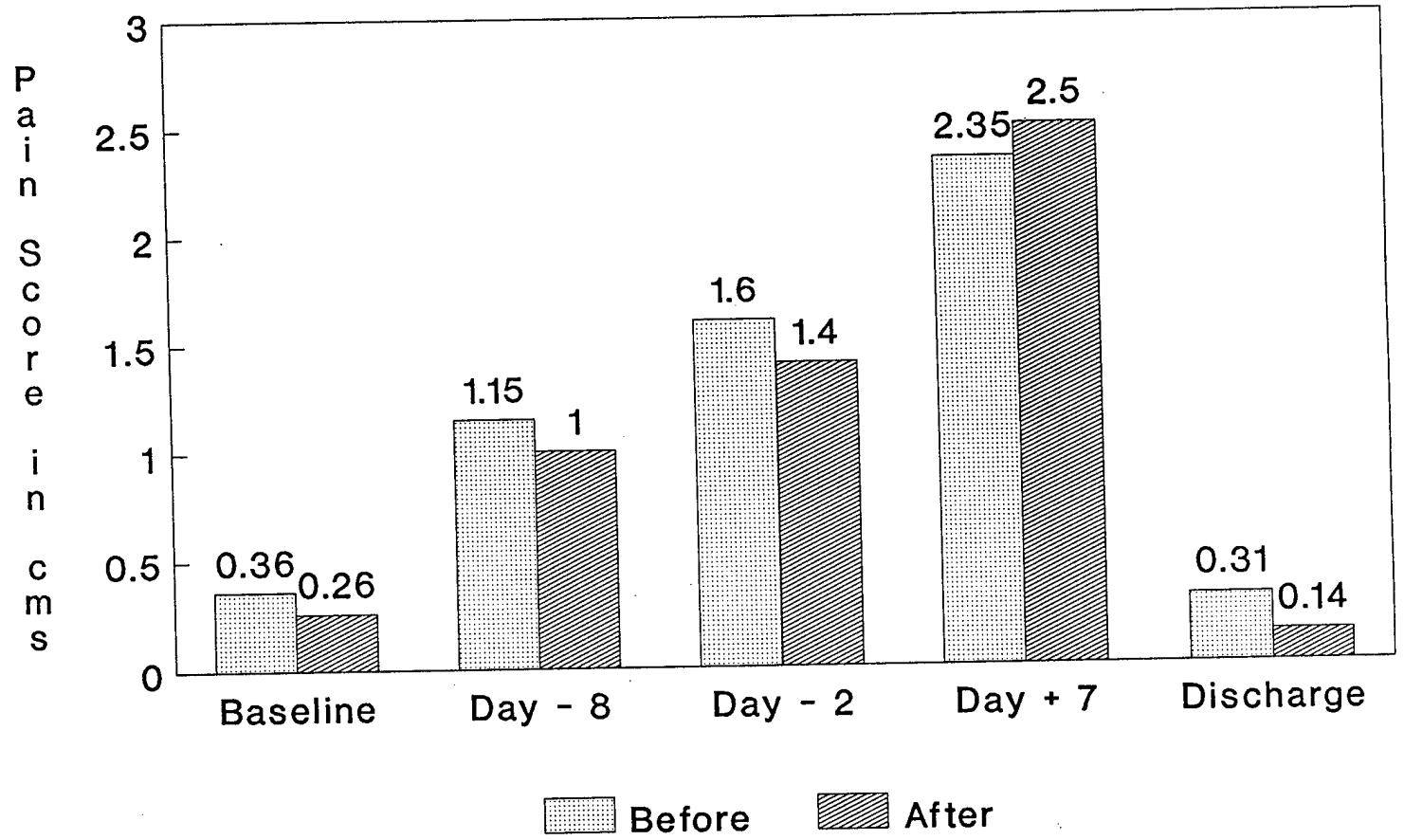


Fig. 2

Relaxation Scores Before & After Intervention (Patients)

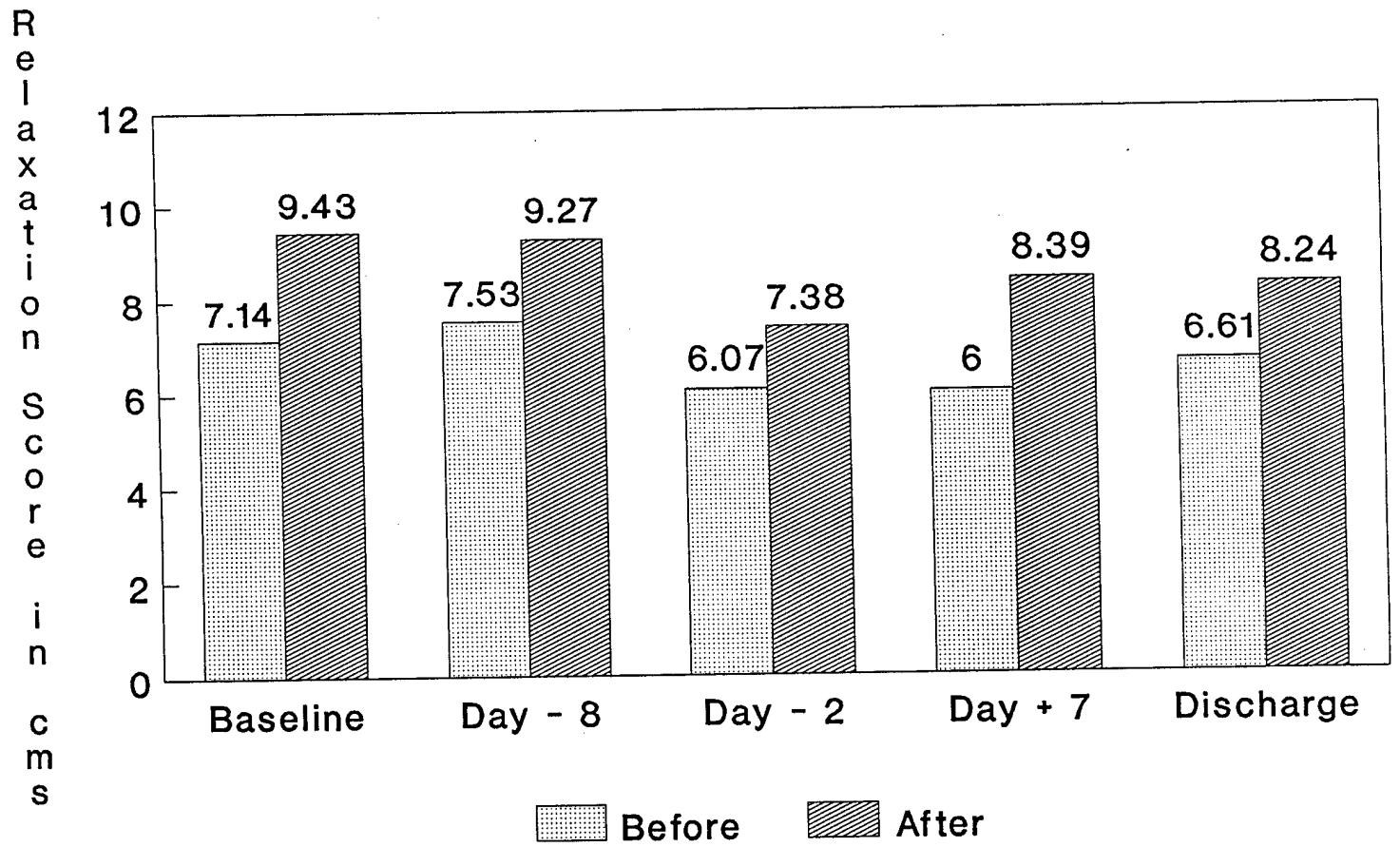


Fig. 3

Relaxation Scores Before & After Intervention (Primary Caregivers)

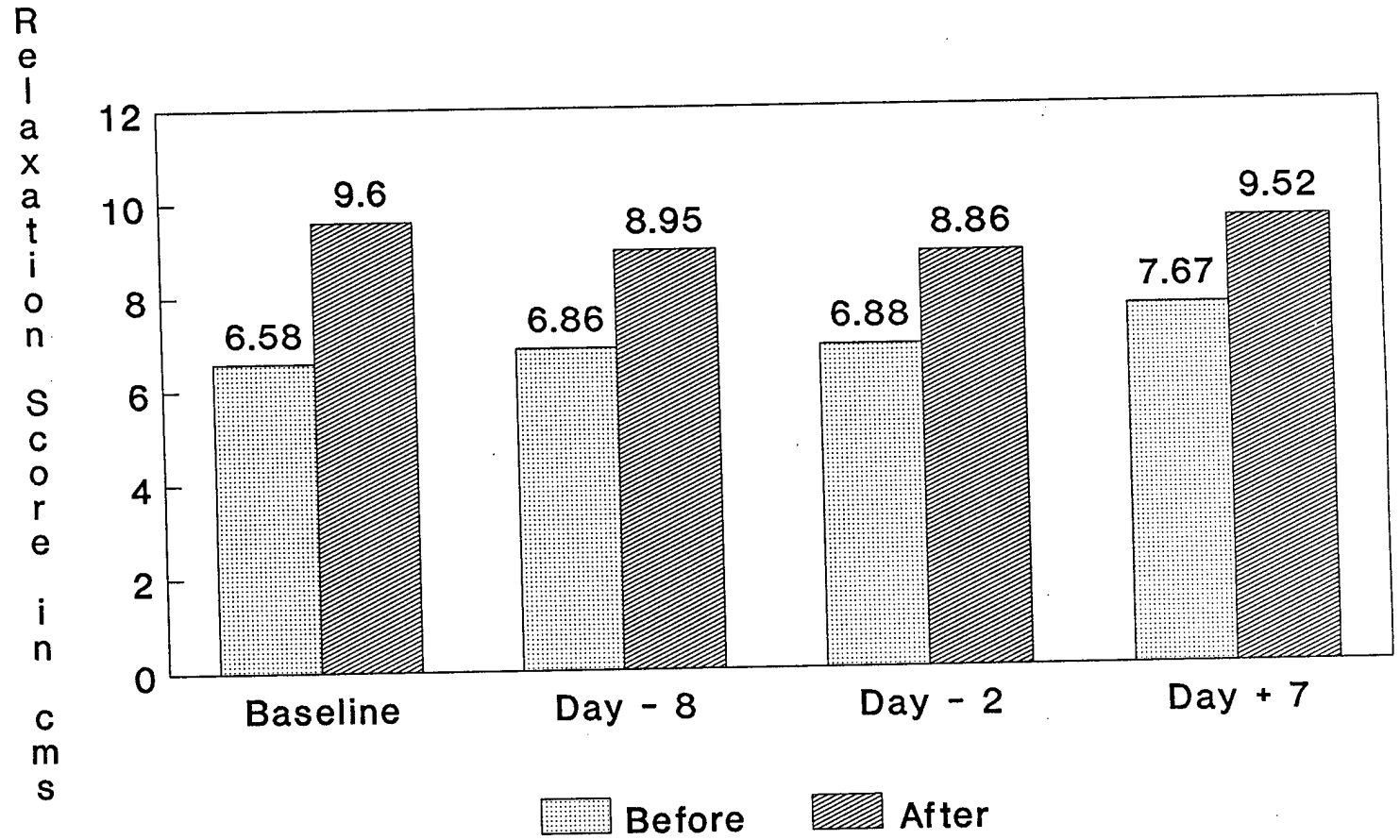


Fig. 4 Effect of CCSP on Breast Cancer Patients Receiving ABMT

Mean Pain (+/- s.d) Scores at Day -2 and +7 from ABMT

(Tx=Treated C=Control)

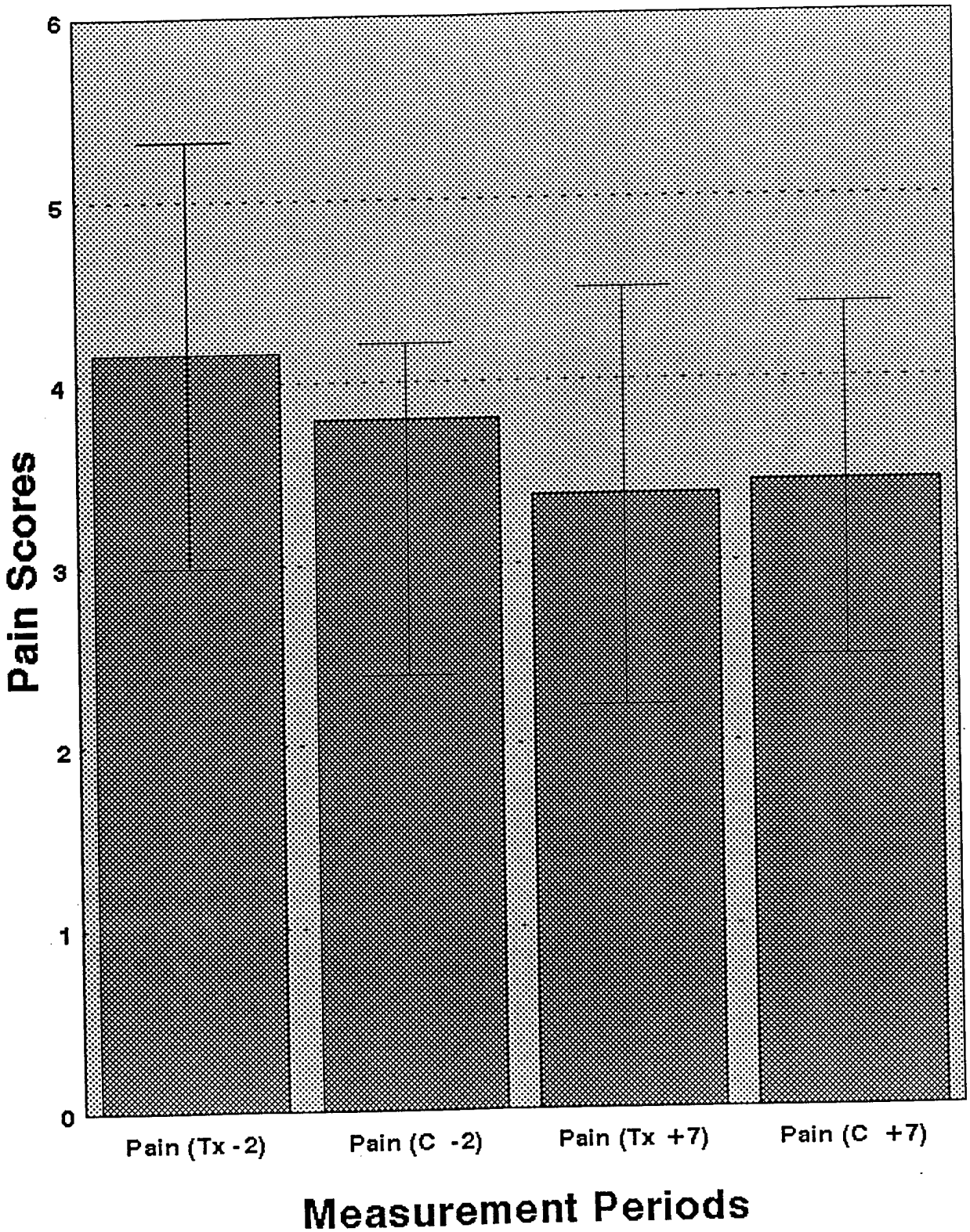


Fig. 5 Effect of CCSP on Breast Cancer Patients Receiving ABMT

Mean Anxiety (+/- S.D) Scores at Day -2 and +7 from ABMT
(Tx=Treated C=Control)

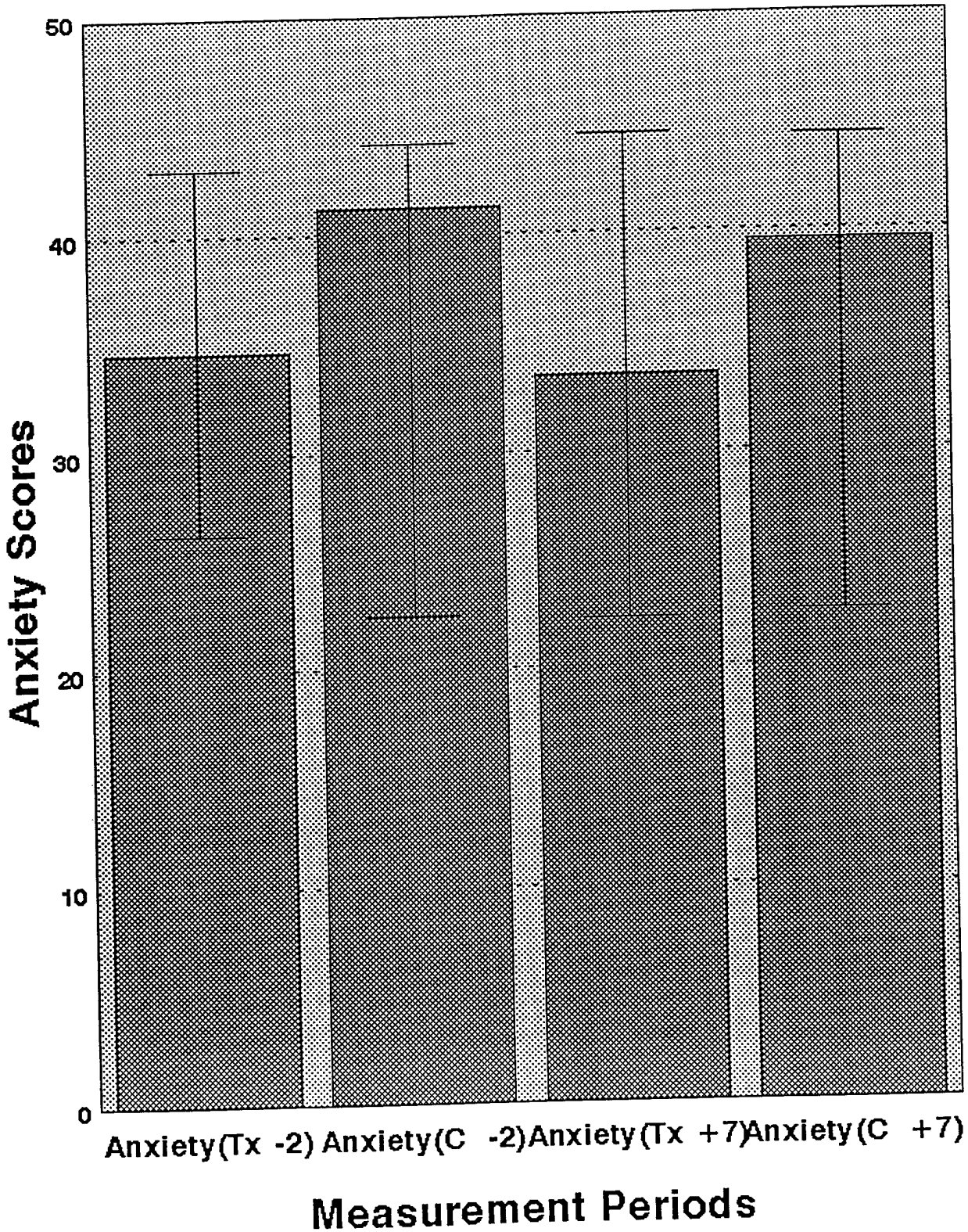


Fig. 6 Effect of CCSP on Breast Cancer Patients Receiving ABMT

Mean Depression (+/- S.D) Scores at Day -2 and +7 from ABMT

(Tx=Treated C=Control)

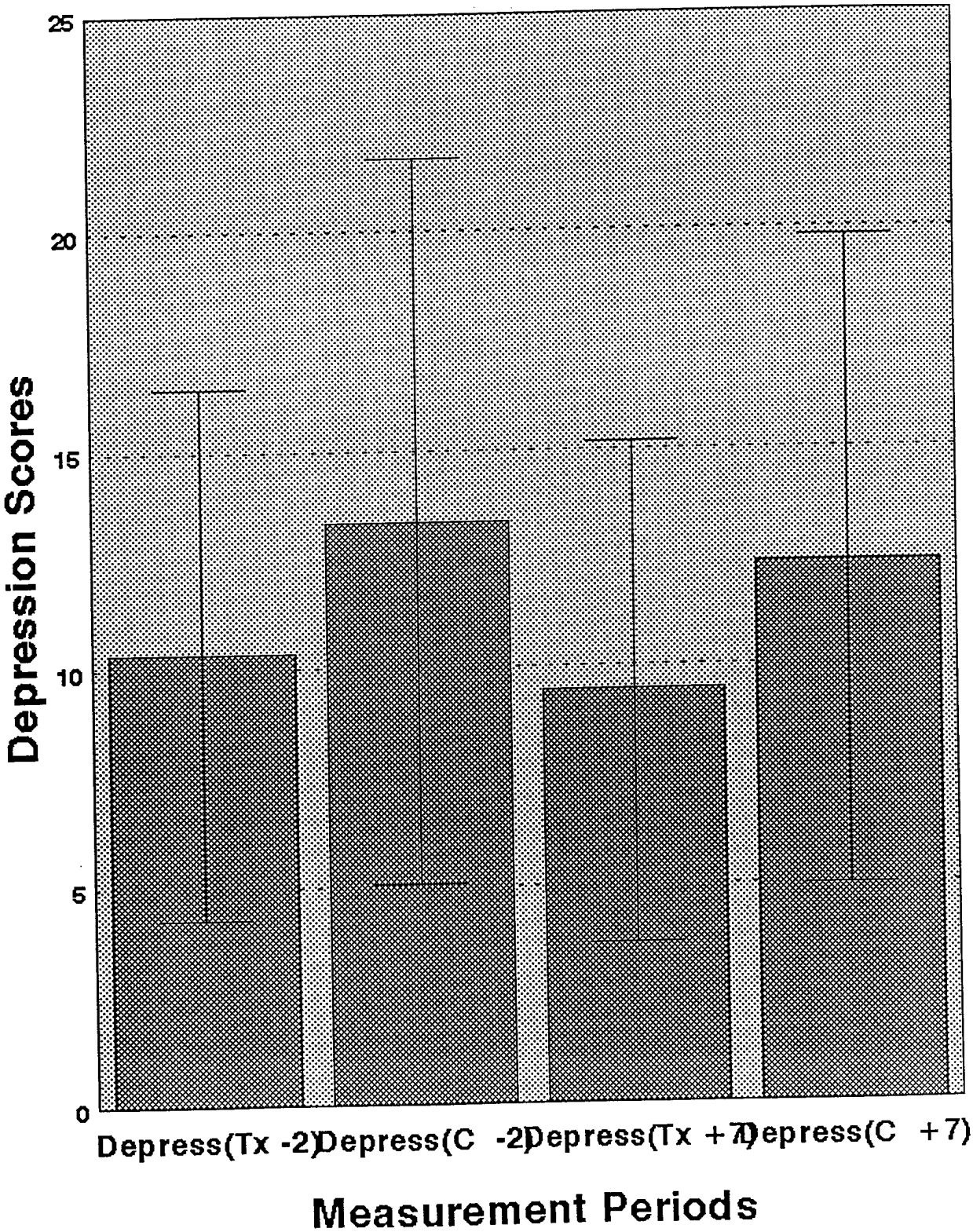
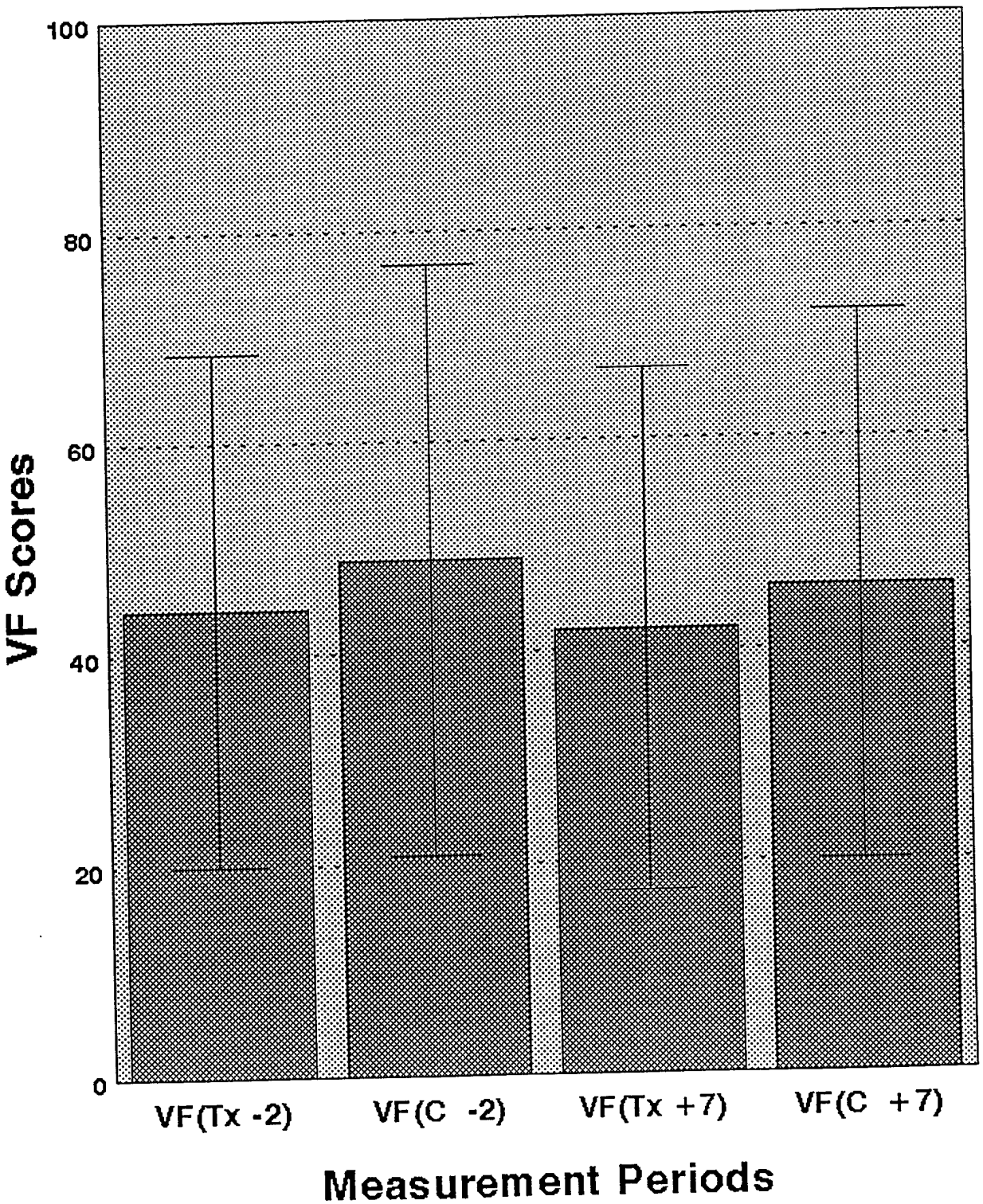


Fig. 7 Effect of CCSP on Breast Cancer Patients Receiving ABMT

Mean (+/- S.D) Scores at Day -2 and +7 from ABMT

VAS Fatigue (Tx=Treated C=Control)

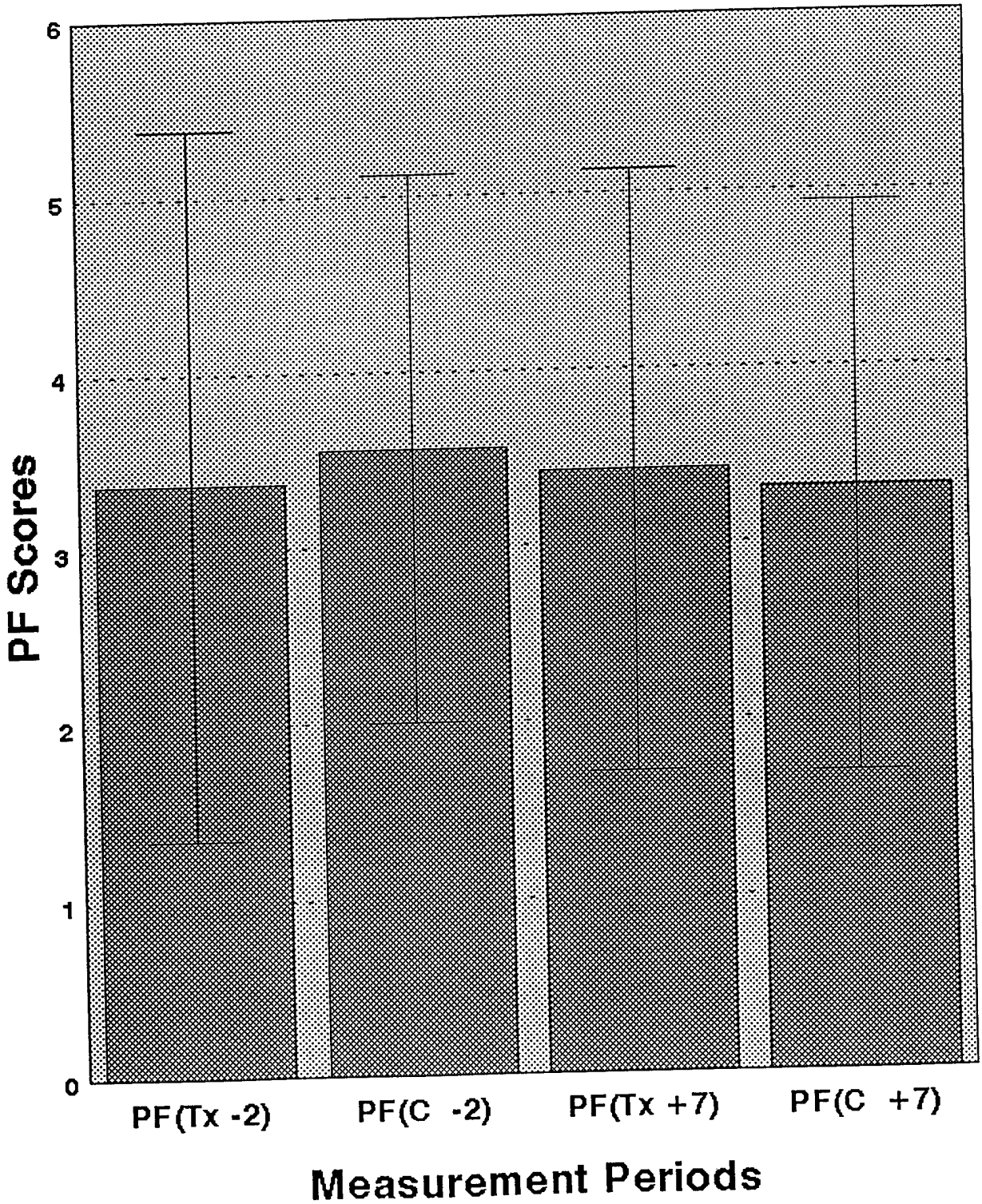


VF (VAS Fatigue)

Fig. 8 Effect of CCSP on Breast Cancer Patients Receiving ABMT

Mean (+/- S.D) Scores at Day -2 and +7 from ABMT

Physical Functioning (Tx=Treated C=Control)

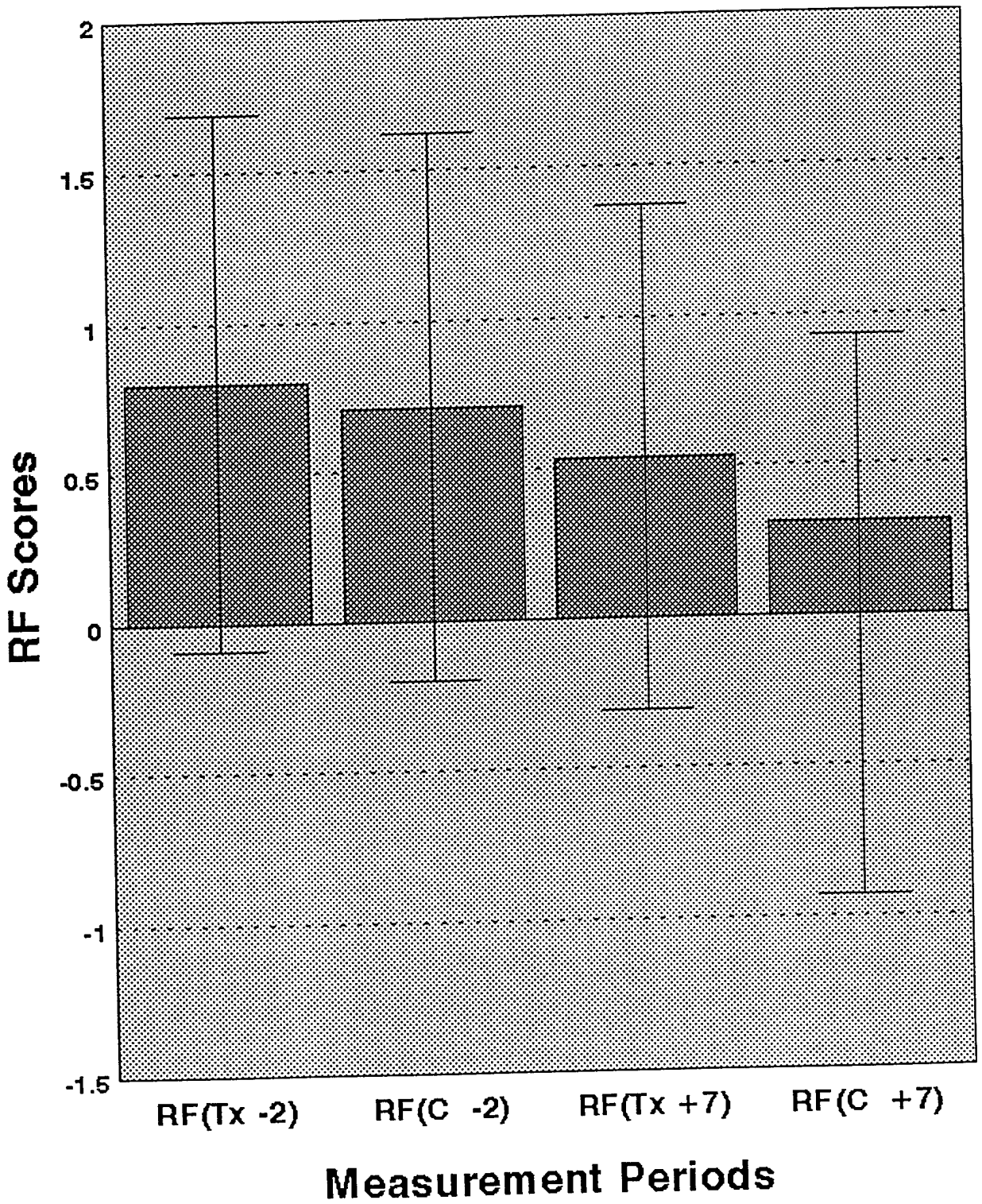


PF (Physical Functioning)

Fig. 9 Effect of CCSP on Breast Cancer Patients Receiving ABMT

Mean (+/- S.D) Scores at Day -2 and +7 from ABMT

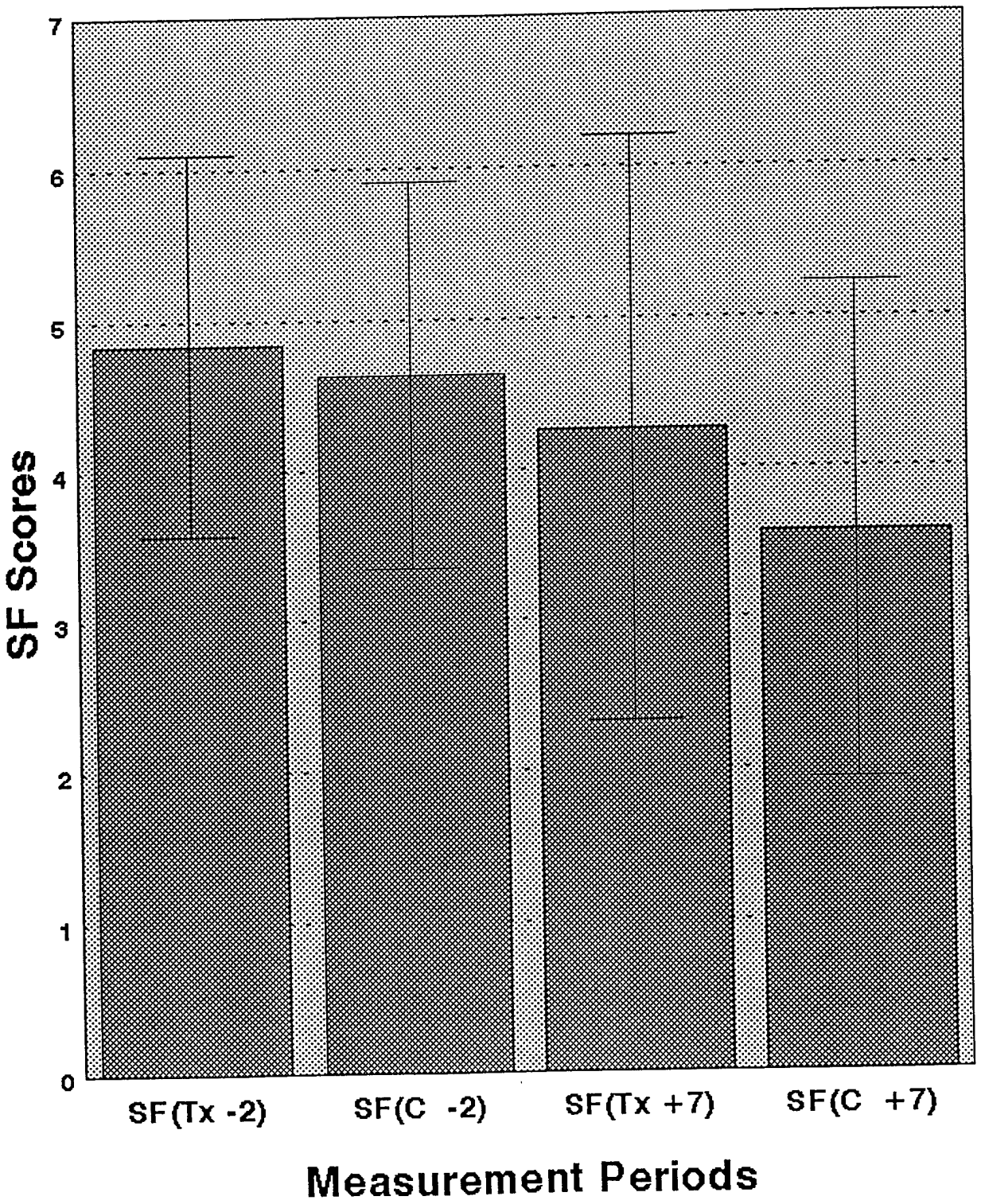
Role Functioning (Tx=Treated C=Control)



RF (Role Functioning)

Fig. 10 Effect of CCSP on Breast Cancer Patients Receiving ABMT

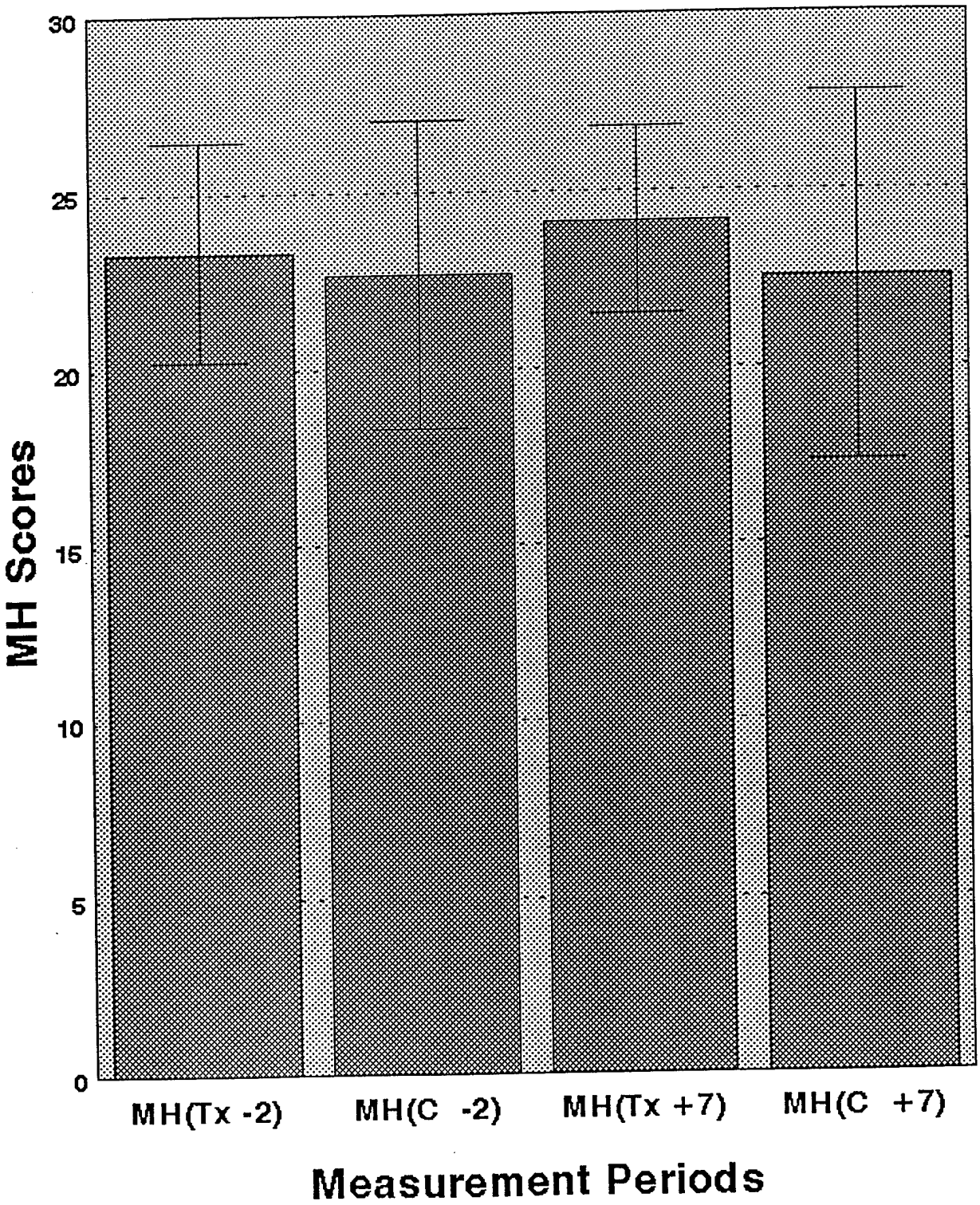
Mean (+/- S.D) Scores at Day -2 and +7 from ABMT
Social Functioning (Tx=Treated C=Control)



SF (Social Functioning)

Fig. 11 Effect of CCSP on Breast Cancer Patients Receiving ABMT

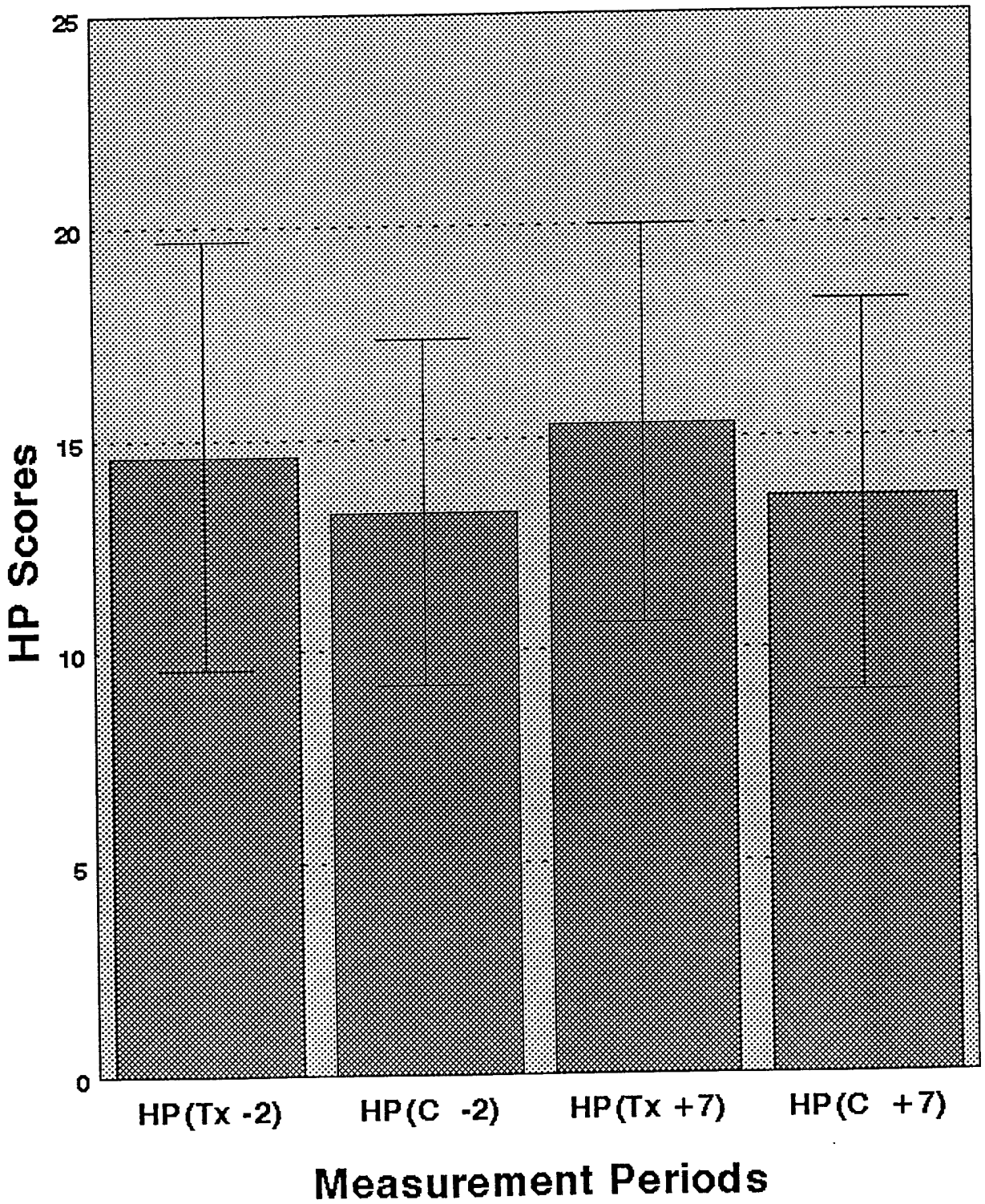
Mean (+/- S.D) Scores at Day -2 and +7 from ABMT
Mental Health Functioning (Tx=Treated C=Control)



MH (Mental Health Functioning)

Fig. 12 Effect of CCSP on Breast Cancer Patients Receiving ABMT

Mean (+/- S.D) Scores at Day -2 and +7 from ABMT
Health Perception (Tx=Treated C=Control)

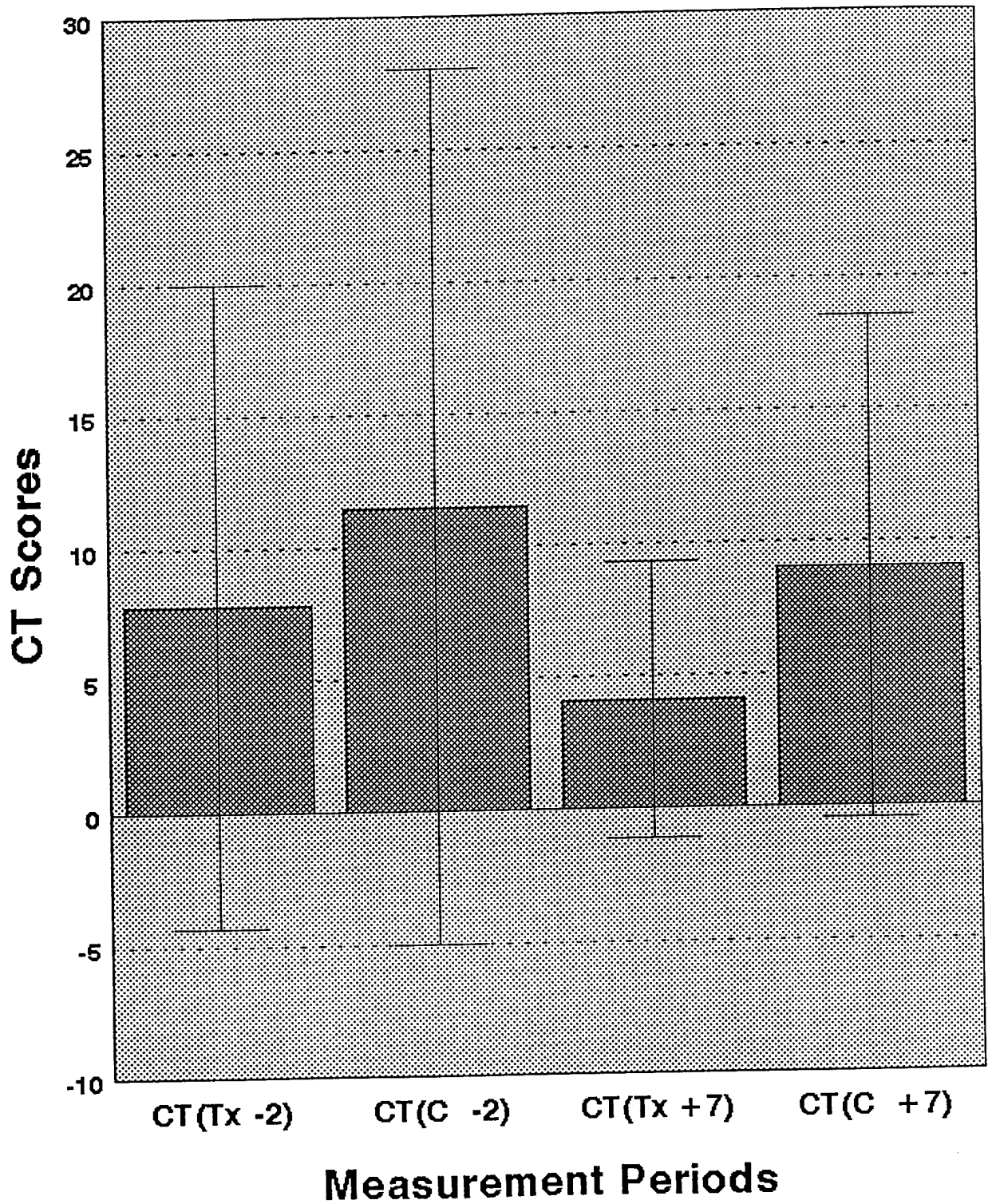


HP (Health Perception)

Fig. 13 Effect of CCSP on Breast Cancer Patients Receiving ABMT

Mean (+/- S.D) Scores at Day -2 and +7 from ABMT

Coping: Catastrophising(Tx=Treated C=Control)

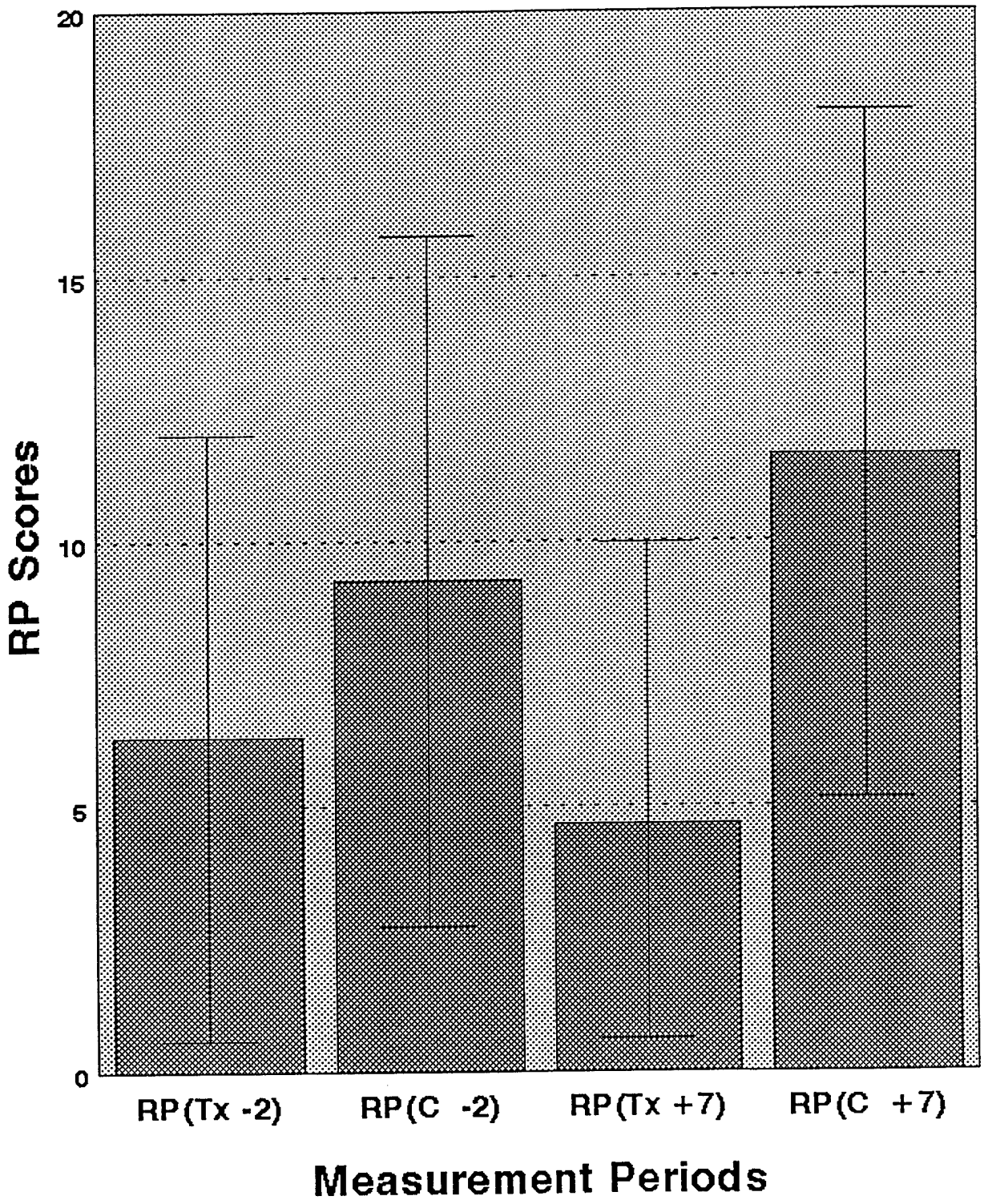


CT (Catastrophising)

Fig. 14 Effect of CCSP on Breast Cancer Patients Receiving ABMT

Mean (+/- S.D) Scores at Day -2 and +7 from ABMT

Coping Subscale: Reinterpreting Pain(Tx=Treated C=Control)

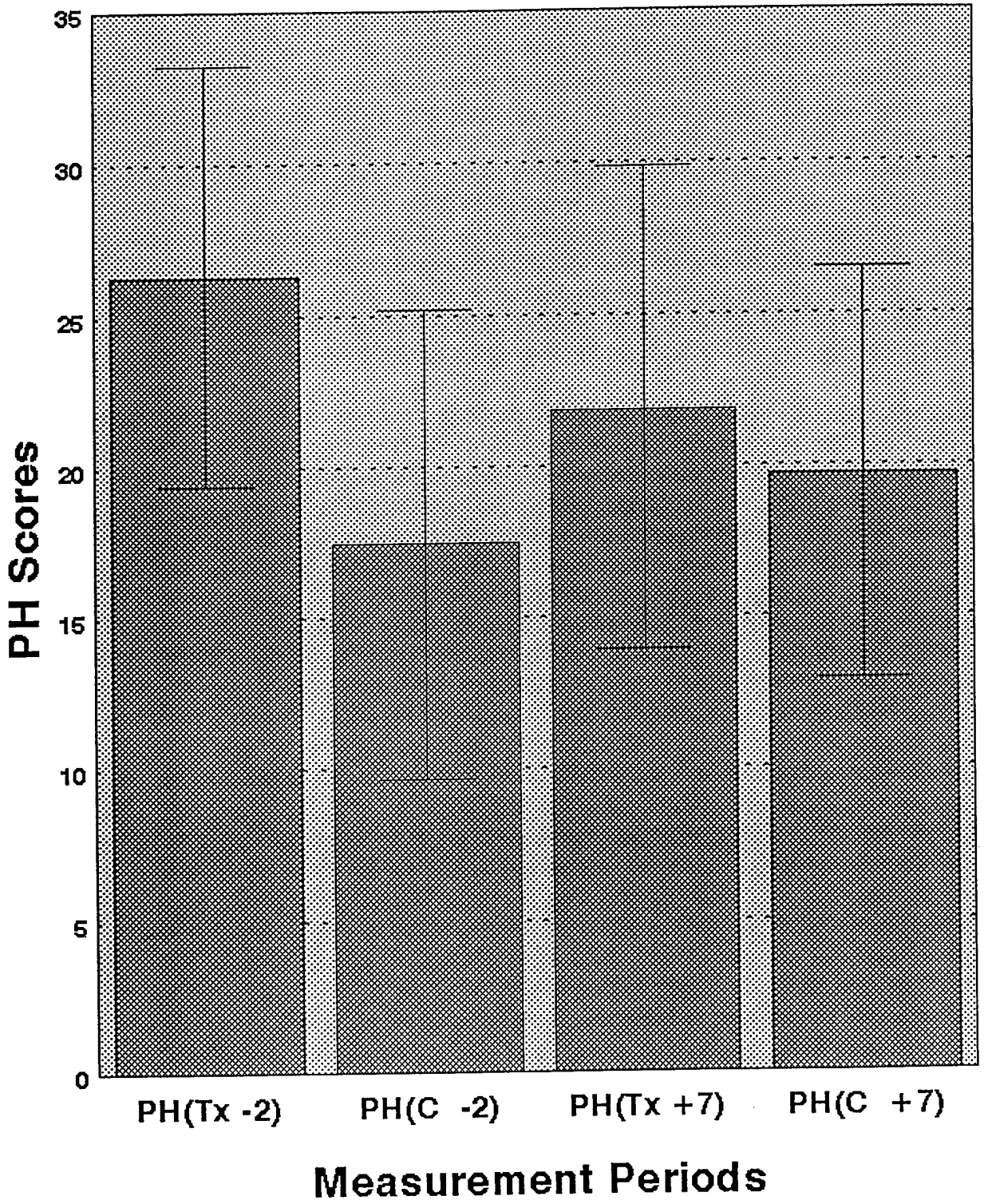


RP (Reinterpreting Pain)

Fig. 15 Effect of CCSP on Breast Cancer Patients Receiving ABMT

Mean (+/- S.D) Scores at Day -2 and +7 from ABMT

Coping Subscale: Praying and Hoping(Tx=Treated C=Control)



PH (Praying and Hoping)

APPENDIX A

A Comprehensive Coping Strategy Program

Presentation: A variety of teaching strategies are used to present the Comprehensive Coping Strategy Program (CCSP) to help promote and maintain breast cancer ABMT patient and PCG interest. Patients, particularly in clinical settings, are likely to experience a range of physical and psychological factors, such as pain, fatigue and anxiety resulting from high psychological stress, which compete with the educator for their interest levels [43]. Consideration was also given to providing the best match between specific content areas and the most appropriate teaching. Oral communication (lecture) has been found most effective in establishing rapport and in teaching new knowledge such as preparatory information, while slide tapes are especially beneficial for abstract concepts. Videotapes are most effective in situations when learning step-by-step procedures with movement is required, such as relaxation techniques with guided imagery [43-44]. A conference/treatment room is used to present the CCSP. This setting has comfortable chairs and adequate space to practice relaxation. The setting is also appropriate for presenting educational materials.

Preparatory Information: The purposes of the CCSP are presented by the instructor using an overhead. A schematic drawing of the symptoms (pain, psychological distress, and fatigue) that patients are known to experience is presented. The instructor reviews the overhead pointing out the relationship among the different symptoms and how they can influence each other. The instructor summarizes the information by stressing that adequate control of pain can lead to decreased psychological distress and a decrease in physical symptoms other than fatigue. The subjects are told that the information presented is based on the experiences of patients who have successfully undergone ABMT. Handouts that cover appropriate information are reviewed and given to the participants: 1) "Ways in Which You Can Participate in Reducing Pain and Psychological Distress, and; 2) "Some General Ways To Increase Control". The above information is presented by the instructor using simple terminology and principles of learning. In order to make sure that the content is presented in a standardized manner, a detailed script and specific overheads are used by the instructor to present this material.

Treatment of Pain: Theoretical Considerations: This part of the CCSP is a slide presentation with an accompanying tape. Interaction between the instructor and the participants is also encouraged. Information covered include the following topics: definition of pain; the three components of pain; a brief explanation of the Gate Control Theory and; theoretical reasons why increasing control through use of coping self-statements and relaxation with imagery can relieve pain and emotional distress. A handout, titled "Ways in Which You Can Participate In Reducing Pain" is reviewed by the instructor and given to the participants at the end of the session. Colorful slides of simple pictures, that symbolize neuro-physiological structures are used when the Gate Control Theory is presented.

Cognitive Restructuring: This segment of the CCSP is also a slide presentation with accompanying tape. This information focuses on the avoidance of catastrophizing, distorted thinking and the use of positive coping self-statements. Cognitive restructuring is directed at modifying thought processes in order to lessen negative sensations and psychological distress. The subjects are taught to conduct an internal dialogue with themselves which directs and refocuses their attention and thinking. This includes descriptions of unproductive catastrophizing statements made by people experiencing discomfort and distress, and then alternatives that may prove more useful in coping. This includes statements such as "I feel relaxed", "I am in control and can handle this situation" and "I know any discomfort I may feel won't last forever". Two handouts, titled "15 Styles of Distorted Thinking to Avoid", and "15 Positive Coping Self-Statements," will be reviewed by the instructor and given to the participants.

Relaxation With Imagery: This part of the CCSP is presented on video-tape in a participant modeling format in which each component of relaxation will be briefly presented, described and demonstrated. The treatment includes a brief progressive muscle relaxation procedure with tense-release cycles being used with specific muscle groups (face, neck and shoulders, stomach and chest, arms and legs). Following these cycles, cue-controlled relaxation will be used involving deep breathing and saying the word "relax" to begin to develop an association between a state of relaxation and these cues. With practice, the cues can then be used to achieve a state of relaxation in a much shorter period of time. Imagery is introduced into the relaxation exercise and participants are permitted to choose the imaginary scene. At the end of the session, the instructor reviews two handouts and gives them to the participants. The handouts are: "Learning and Using Relaxation Therapy" and "Benefits of Relaxation Therapy". The instructor will also give the patient and PCG a small hand-held audiotape recorder (Walkman) with two sets of ear phones and an audiotape. The purpose of the tape is to guide the participants in active participation in the relaxation exercise. The participants are instructed to review all handouts and to practice the relaxation exercise, using the 15 minute audiotape at least every day and prior to stressful events. The subjects are instructed how to review the handouts and record their use of the audiotape in a diary.

Reinforcement of CCSP: The reinforcement of the CCSP includes: review of the patients and PCGs diaries, responding to any questions that the subjects have concerning the CCSP; measuring relaxation prior to and post reinforcement of the CCSP; reviewing all handouts with the subjects; and having the subjects listen to the 15 minuteaudiotape with the relaxation exercise withimagery. Reinforcement of the CCSP takes about 30 minutes.